



Europäisches Patentamt
European Patent Office
Office européen des brevets



Publication number:

0 657 140 A1

EUROPEAN PATENT APPLICATION

Application number: **93309280.1**

Int. Cl.⁸: **A61B 17/22**

Date of filing: **22.11.93**

Priority: **12.11.93 US 147471**

Date of publication of application:
14.06.95 Bulletin 95/24

Designated Contracting States:
**AT BE CH DE DK ES FR GB GR IE IT LI LU MC
NL PT SE**

Applicant: **Fischell, Robert E.**
14600 Viburnum Drive
Dayton,
Maryland 21036 (US)

Inventor: **Fischell, Robert E.**
14600 Viburnum Drive
Dayton,
Maryland 21036 (US)

Representative: **Lambert, Hugh Richmond**
D. YOUNG & CO.,
21 New Fetter Lane
London EC4A 1DA (GB)

Catheter system for forming a passage through an arterial blockage prior to atherectomy or angioplasty.

The catheter system is designed for penetration of tight stenoses or total occlusions (called blockages) as a precursor to balloon angioplasty, atherectomy, or any other vessel opening means that requires an initial passageway, and comprises a

catheter (20) carrying at its distal end a pointed tool, e.g. an auger (30) that may be used to open up plastic deformation of the plaque rather than by excision.

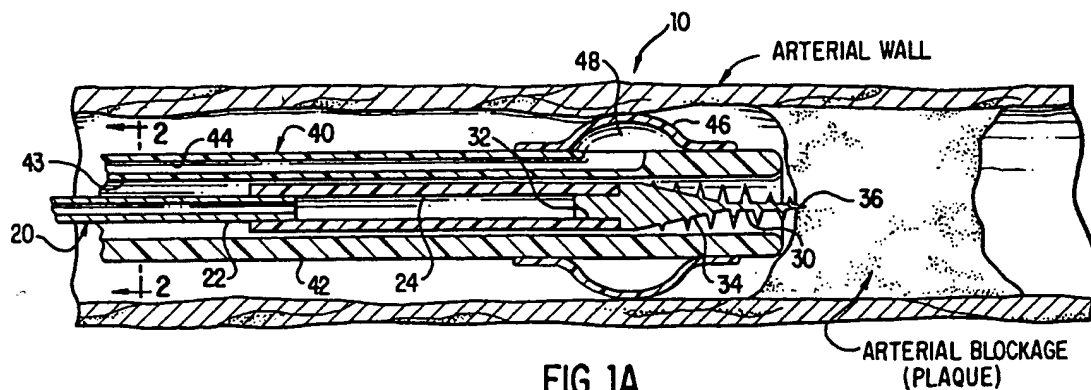


FIG. 1A

EP 0 657 140 A1

This application relates to a catheter system, herein referred to as the Dottering Auger Catheter (DAC) system which may be used to penetrate blockages, e.g. within an artery, so as to make a first passageway prior to balloon angioplasty or atherectomy.

As used herein, the term "dottering" refers to the process of forming and enlarging a hole in a blockage by means of a tapered tool which forms and enlarges the hole by a process of compaction of the material forming the blockage, rather than by excision, i.e. by a process of angioplasty.

Balloon angioplasty and atherectomy are well known modalities for opening vessels of a human body particularly arteries. However, if there is an arterial blockage which cannot be penetrated by a guide wire and/or a balloon angioplasty or atherectomy catheter, surgical bypass vessel grafting is usually required to restore adequate blood flow to that blocked artery. Although lasers have been used for making a passageway, (even through a total blockage) laser equipment is expensive and laser treatment can result in removal of tissue from the arterial wall which could require surgical repair.

The present invention resides in a catheter system which makes possible the penetration of tight stenoses or total occlusions (called blockages) as a precursor to balloon angioplasty, atherectomy, or any other vessel opening procedure that requires an initial passageway.

In its broadest aspect, the invention resides in a catheter system for opening up a passageway in a blockage in an artery or similar vessel in the body, the system comprising an elongate, preferably tubular catheter insertable into the artery or similar vessel through an incision in the body at a point remote from the blockage and advanceable therealong until its distal end reaches the blockage, the catheter carrying at its distal end a tool member having a sharply pointed nose which can be advanced into the blockage to form an initial hole therein, and a conical tapering surface rearwardly of the nose which serves to enlarge the hole by a process of compaction (angioplasty) as the tool member is advanced into the blockage.

Preferably the catheter is a torqueing catheter and the tool member is in the form of a pointed auger with an external screw thread which serves to advance the tool into the blockage as the catheter is rotated.

In the preferred systems, a centering catheter is used to guide the tool through the artery and to locate the tool centrally of the artery at the site of the blockage. Various means may be provided on the distal end of the centering catheter to enable accurate location and centering of the tool at the site of the blockage.

In one embodiment, the centering catheter employs a distally located inflatable balloon mounted on a catheter tube to center the distal end of the auger catheter just proximal to the blockage. The purpose of the auger catheter is to penetrate through the blockage by means of a self-tapping screw at the catheter's distal end. Once the first thread of the screw is pushed into the blockage, rotation of the catheter will cause the screw to advance through the blockage assisted, if necessary, by further axial pressure on the auger. When the auger has formed a passageway through the blockage, it is removed either leaving in place a guide wire that forms a part of the catheter system or enabling a separate guide wire then to be advanced into the artery and through the blockage. With that guide wire in place through the newly opened passageway, the centering catheter can be removed and is replaced by a conventional balloon angioplasty or atherectomy excision catheter which can then be used to enlarge the passageway in a conventional manner thus restoring adequate blood flow through the artery.

An advantage of the DAC system of the invention is that, if the auger inadvertently penetrates through the arterial wall, it can be withdrawn without the removal of tissue from the vessel wall. Hence, the vessel wall would typically seal itself without the requirement of surgical repair. If a laser were used to open a blockage, inadvertent passage of the beam through the arterial wall would result in wall tissue removal which could require surgical repair.

Other embodiments of the DAC system described herein include various non-balloon centering catheters and a needle-tipped penetrating catheter for pushing through the blockage, and designs which include various guide wires as part of the DAC system.

Also described herein are embodiments which operate without a centering catheter, or without a screw thread, i.e. which can simply be pushed through the blockage by axial pressure applied to the catheter.

Furthermore, if a guide wire (without the DAC system) is used to try to penetrate through a blockage, it occasionally causes intimal dissection. The present invention using a centering catheter and an auger screw is more likely to be able to penetrate through the blockage without causing intimal dissection.

Other constructional features and advantages of the catheter system of this invention will become apparent from the detailed description presented hereinafter and with reference to the accompanying drawings, in which:

Figure 1A is a longitudinal cross section of the distal portion of a preferred catheter system ac-

cording to the invention and located within an artery having a total blockage.

Figure 1B is a longitudinal cross section of a different form of penetration catheter that can be used within a centering catheter to form an initial hole in the blockage prior to atherectomy or balloon angioplasty.

Figure 2 is a transverse cross section of the system at position 2-2 of Figure 1A.

Figure 3 is a longitudinal cross section at the system's proximal end showing a handle for applying push and torque to the auger catheter.

Figure 4 is a longitudinal cross section of another embodiment of a catheter system according to the invention and showing a centering catheter with a uniform outer diameter.

Figure 5 is a longitudinal cross section of another centering catheter for use in the system of this invention and having a spherical protrusion near its distal end.

Figure 6 is a longitudinal cross section of another centering catheter for use in the system of this invention and having a plurality of expandable spokes near the catheter's distal end.

Figure 7 is a longitudinal cross section of a centering catheter for use in the system of this invention and having a steel, flat-wire, helical coil interior structure.

Figure 8 is a longitudinal cross section of the distal portion of yet another embodiment of a catheter system according to the invention and positioned within an artery having a total blockage.

Figure 9 is a cross section of a modified version of the invention without a centering catheter but with a specially shaped guide wire.

Referring to the drawings, Figure 1A is a longitudinal cross section showing a distal portion of the DAC system 10 within an artery which has a total occlusion (blockage). The DAC system 10 consists of a Dottering Auger Catheter (DAC) 20 and a centering catheter 40. The DAC 20 consists of a proximal steel tube 22, a flexible catheter section 24 and a distal, self-tapping screw 30. The proximal end of the tube 22 extends outside of the patient's body (see Figure 3) where a conventional handle can be mounted which facilitates the operator's ability to simultaneously apply a rotational torque (twist) and a push force to the DAC 20. The tube 22 is joined at its distal end to the flexible catheter section 24 which is joined at its distal end to the auger screw 30. Thus, the push and twist imparted at the proximal end of the tube 22 will be imparted to the screw 30 so that it will screw itself into the arterial blockage.

The self-tapping screw 30 consists of a shoulder 32 which is joined (typically by an adhesive or by brazing, soldering or welding) to the catheter

section 24. Further the screw 30 has a conical section 34 which makes a progressively larger central opening in the plaque of the blockage as the screw 30 is advanced by rotating it and pushing it forward through the blockage. This process is called "Dottering" and is accomplished by plastic deformation of the blockage tissue by the self-tapping screw 30 and the distal end of the flexible section 24 without any significant tissue removal. As seen in Figure 1A, it is important that there is a smooth transition of the outer surface of the conical section 34 onto the outer surface of the distal end of the flexible section 24 so that the screw threads can readily pull through the blockage tissue without excessive torque applied to the auger catheter 30.

The screw 30 also has an extremely sharp point 36 at its distal end to assist in pushing through the plaque. The screw 30 would typically be 0.5 to 2 cm. long and 0.2 to 2.0 mm in diameter.

The flexible section 24 of the auger 20 could be fabricated from a plastic such as nylon, polyethylene, polyurethane, etc. or it could be fabricated from braided metal material or made from a flat metal wire coil as is well known in the art of torque cables. The length of the flexible section 24 would typically be between 5 and 50 cm, and the outside diameter would typically be between 0.2 and 2.0 mm with a wall thickness between 0.01 and 0.05 mm.

The steel tube 22 would typically have a wall thickness between 0.05 and 0.30 mm and would be fashioned from a material such as type 304 stainless steel. The same stainless steel can be used for all other metal parts of the DAC system 10 such as the screw 30.

The centering catheter 40 consists of a plastic tube 42 having a central lumen (or passageway) 43 through which the DAC 20 can be passed, and a second lumen 44 through which a fluid such as air or contrast medium can be passed in order to inflate the balloon 46 that is located near the distal end of the centering catheter 40. Such a fluid will fill the chamber 48 that lies internal to the balloon 46 thus centering the distal ends of the tube 42 and the central lumen 43 within the artery. Thus, the distal end of the DAC 20 which lies within the lumen 43 will also tend to be centered so that the point 36 will be centered onto the proximal surface of the blockage. Thus the DAC 20 can be pushed through near the blockage's center which reduces the possibility that the screw 30 will penetrate through the arterial wall. Even if it does penetrate through an arterial wall, the screw 30 could be screwed back without resulting in serious harm to the patient. This is because no piece of arterial wall would actually be removed by the screw 30 as would be the case if a laser beam or cutting blade

actually removed a piece of the arterial wall. An inadvertent penetration of the arterial wall with the distal end of the DAC 20 would tend to be self-sealing.

Figure 1B shows an alternative embodiment of the DAC 20. Specifically, the penetration catheter 21 shown in Figure 1B would pass through the central passageway of a centering catheter and could penetrate through a blockage by pushing or with the assistance of ultrasonic vibration applied at its distal end. Like the DAC 20, the penetration catheter 21 would not remove tissue and would be centered by the centering catheter as it passes through the blockage which reduces the possibility of intimal dissection and/or arterial wall perforation.

Figure 2 shows a cross section of the DAC system 10 at position 2-2 of Figure 1A. At the center is the auger tube 22 which can slide within the central lumen 43 of the catheter tube 42. The lumen 44 forms a passageway for fluid to inflate or deflate the balloon 46.

Figure 3 illustrates the proximal end of the DAC system 10 which lies outside of the patient's body. The proximal end of the tube 42 would terminate in a Tuohy-Borst gland or hemostasis valve 47 formed as a soft elastomer seal. This valve 47 seals against the outer surface of the steel tube 22. A side arm 45 near the proximal end of the tube 42 has a lumen 49 which is in fluid communication with the balloon lumen 44. Thus inflation and deflation of the balloon 46 (of Figure 1A) can be accomplished by injecting fluid through the lumen 49 of the side port 45. The design of the valve 47 and side arm 49 would be typical of valve and side port designs used at the proximal end of the introducer sheaths which are well known in this art. Another side arm (not shown) could be used to deliver contrast medium to the distal end of the lumen 43.

A steel or plastic handle 23 formed as shown in Figure 3 would be joined by spot welding through the proximal end of the tube 22 onto the extension 25 of the handle 23. Other handle designs could be accomplished by plastic molding or adhesive bonding onto the proximal end of the tube 22.

The total lengths of the centering catheter 40 and the DAC 20 can be predetermined so that the length "L" shown in Figure 3 is an exactly known length when the point 36 is co-extensive with the distal end of the centering catheter 40. For example, with the geometry of the distal end of the DAC system 10 as shown in Figure 1A, when the point 36 extends (let us say) 1.0 mm beyond the distal end of the centering catheter 40, then the dimension "L" might be 2.0 cm. Thus the most that the screw 30 could be advanced through a blockage would be 3.0 cm. Further, the outer surface of the

tube 22 within the length "L" shown in Figure 3 could have marks which indicate to the doctor how far the point 36 has advanced beyond the centering catheter's distal end.

The procedure for using the DAC system 10 based on the embodiment of Figures 1A, 2 and 3 would be as follows:

- (1) Angiography would be used to indicate an arterial blockage.
- (2) A 1.0 mm diameter guide wire would then be advanced through an introducer sheath at the patient's groin (and possibly through a guiding catheter) until the guide wire's distal end touches the proximal surface of the blockage.
- (3) The centering catheter would then be advanced over the guide wire until its distal end is in contact with the blockage's proximal surface.
- (4) The guide wire would then be removed and the balloon would be inflated to a moderate pressure such as 0.3 atmospheres.
- (5) Contrast medium would then be injected through the central lumen of the centering catheter to verify its position in the artery. The length of the blockage would be noted.
- (6) A DAC having a diameter of 1.0 mm would then be advanced through the centering catheter until its distal end was in contact with the blockage.
- (7) Using the scale at the proximal end of the tube 22, the auger screw would be advanced a distance somewhat greater than the length of the blockage by turning the auger's handle in a known direction such as clockwise while pushing it forward.
- (8) The auger would then be removed and contrast medium would be injected through the central lumen of the centering catheter to verify that the DAC had dotted a passageway through the blockage.
- (9) A guide wire for an angioplasty balloon catheter (typically 0.34 mm diameter) would then be advanced through the centering catheter and through the newly formed passageway in the blockage.
- (10) The centering catheter would then be removed and a balloon angioplasty or atherectomy procedure would be performed.

Figure 4 shows an alternative embodiment of a centering catheter 50 having a uniform outer diameter which can be used to adequately center an auger catheter 60 inside a comparatively small artery. The centering catheter 50 is considerably simpler and therefore less costly and complex in operation as compared to the balloon centering catheter 40 of Figure 1A. If, for example, the internal diameter of the artery is 2.0 mm, then a centering catheter 50 could have an outside diameter of 1.9 mm, a wall thickness of 0.4 mm, and the auger

catheter 60 could have an outer diameter of 1.0 mm (0.039 inches) which could readily slide within that centering catheter.

Figure 5 shows another design of a centering catheter 70 which employs a spherically shaped bulge 72 near the catheter's distal end. This catheter 70 could have the same dimensions as the catheter 50, except the outer diameter "D" of the bulge 72 would lie between 2.0 and 6.0 mm. When pushed through a guiding catheter or introducer sheath, the bulge 72 could collapse to slide within the inside cylindrical surface of that guiding catheter or sheath. Once in an artery, the bulge would expand to accurately center the distal end 74 of the centering catheter 70 in an artery just proximal to a blockage. The distal end 74 could be made radiopaque so that it could be visualized with fluoroscopy.

Figure 6 illustrates still another embodiment of a centering catheter 80 which has a plurality of spokes 84 near its distal end which connect to a distal ring 86. In its normal position, the spokes 86 of this 4 spoke design (3 spokes are shown in this longitudinal cross section) bulge out slightly. However, when the distal ring 84 is pushed against a blockage, the spokes 86 will bulge in an outward direction as shown by the dotted lines 84' in Figure 6, and the distal ring 86 will move in a proximal direction to a position as indicated by the dotted lines 86'.

Figure 7 shows another centering catheter 88 in which the interior structure is a helical, flat-wire steel coil 89. One purpose of the coil 89 is to prevent the auger screw threads from catching on the interior plastic surface of the centering catheter 88. Such a metal helical coil 89 would be covered on its outer (and possibly inner) surface by a plastic tube 87 so that the centering catheter would slide smoothly within an artery. Another purpose of the coil 89 is to make the distal end of the centering catheter steerable so that the distal tip of the auger could be aimed at some angle relative to the blockage to avoid penetrating the wall in a curved artery. Composite materials catheter designs of this type are described in detail in U.S. Patent No. 5,180,376.

Another embodiment of the present invention is shown in Figure 8. In this embodiment, the DAC system 90 includes a centering catheter 91, a Dottering Auger Catheter (DAC) 94 and a guide wire 98. The centering catheter 91 has an elongated, plastic body 92 and a radiopaque marker ring 93 at or near its distal end. The design of the distal region of the centering catheter 91 could be similar to any of the centering catheters previously described herein. The DAC 94 consists of a flexible section 95 whose distal end is joined to the proximal end of a self-tapping auger screw 96. The

outer surface at the proximal end of the screw 96 is continuous with the distal end of the flexible section 95, thus forming an ideal shape for Dottering through an arterial blockage. The outer surface of a distal portion of the DAC 94 may advantageously be coated with a lubricious coating to decrease the stress on the blockage tissue during rotation of the screw 96 as the DAC 94 is advanced through the blockage tissue. The ring 93 and the screw 96 are ideally made from a highly opaque, dense metal such as tantalum or an alloy of platinum or gold. Such objects appear to be very bright in fluoroscopy, thereby helping the interventional cardiologist to locate the tips of the centering catheter 91 and DAC 94 relative to the arterial blockage.

The DAC system 90 also includes a guide wire 98 that can be moved slideably through a passageway that lies at the center of the DAC 94; which passageway includes a hole through the center of the screw 96. Typically a 0.35 mm plus or minus 0.10 mm diameter guide wire would be used, and the hole in the screw would typically be made 0.02 to 0.05 mm larger in diameter as compared to the guide wire 98. The proximal end of the DAC system 90 would be of a similar design to that shown in Figure 3 except that the guide wire 98 would extend through a seal such as a hemostasis valve in the DAC's proximal handle. By using a guide wire 98 to center the DAC 94, it is possible to eliminate the need for the centering catheter 91.

As shown in Figure 8, many occlusions have a funnel like entry cone which can lead into what might be the remains of a true lumen of the blockage. This true lumen may actually exist, or it could be the last tissue that stenosed making it somewhat softer than the older parts of the blockage. The design shown in Figure 8 is ideally suited for placing the screw 96 through this true lumen. This guide wire design of the DAC system is desirable to reduce the possibility of intimal dissection of the plaque away from the arterial wall. A lubricious coating at the distal end of the DAC 94 also decreases the possibility of intimal dissection. A procedure the DAC system 90 for Dottering through a blockage should be as follows:

- (1) The guide wire 98 is advanced through the arterial system but cannot penetrate through a blockage.
- (2) The centering catheter 91 and the DAC 94 are advanced together over the guide wire 98 until fluoroscopy reveals that their distal ends are contacting the blockage's proximal surface.
- (3) A handle at the proximal end of the DAC 94 is pushed forward while being rotated to advance screw 96, and a distal section of the flexible section 95 through the blockage.
- (4) The guide wire 98 is advanced through the blockage as the screw 96 moves forward or it

can be advanced after a Dottered passageway has been formed in the blockage.

(5) The centering catheter 91 and the DAC 94 are then removed out of the body and a balloon angioplasty or atherectomy catheter is then advanced over the guide wire 98 to further open the arterial lumen with the blockage.

It should be understood that it might be possible to place a guide wire across the true lumen of the blockage, but not possible to advance a balloon angioplasty or atherectomy catheter through the remaining very tight stenosis. In such a case, the balloon angioplasty or atherectomy catheter would be pulled out with the guide wire being left in place across the blockage. The DAC 94 could then be advanced over the guide wire and used to enlarge the diameter of the true lumen. In this case, the centering catheter 91 might or might not be used. The DAC 94 can Dotter a sufficiently large diameter in the lumen of the stenosis to allow for the passage of a balloon angioplasty or atherectomy catheter.

Figure 9 shows a special guide wire 99 having a very sharp point at its distal end and shoulder 100 that engages the distal tip of the screw 101. This design would operate by having both the guide wire 99 and the screw 101 advanced together through the blockage. The design of Figure 9 would preclude the possibility that blockage tissue would be caught in the hole of the screw 101 as it Dotters through the blockage.

Although the discuss herein was concerned with opening an arterial blockage, this technique could also be applied to opening other blockages of vessels in living bodies such as bile ducts, fallopian or bronchial tubes, urethras, etc. through which it is desired to make a passageway. Furthermore, the centering and balloon dilation functions could both be accomplished with the same balloon angioplasty catheter. Still further, the auger device could be used without a centering catheter (for example as shown in Figure 9) and it would still function to open an occluded blood vessel or duct.

Various other modifications, adaptations, and alternative designs are of course possible in light of the above teachings. Therefore, it should be understood at this time that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.

Claims

1. A catheter system for forming and enlarging a hole in a blockage blocking an artery or similar vessel in the body, the system comprising an elongate catheter (20) insertable into the artery or similar vessel through an incision in the body at a point remote from the blockage and

advanceable therealong until its distal end reaches the blockage, the proximal end of the catheter remaining external to the body, characterised in that the catheter carries at its distal end a tool member (30, 60, 96, 101) having a sharply pointed nose (36, 99) which can be advanced into the blockage to form an initial hole therein and a conical tapering surface rearwardly of the nose which serves to enlarge the hole by a process of compaction, rather than excision, as the tool member is advanced into the blockage.

2. A catheter system according to claim 1, characterised in that the tool member (30, 60, 96, 101) is connected to the catheter (20) by means of an intermediate flexible connecting member (24).

3. A catheter system according to claim 1 or 2, characterised in that the tool member (30, 60, 96, 101) is non-rotatably connected to the distal end of the catheter (20) and in that the catheter (20) is a torqueing catheter which enables the tool member to be rotated about its axis as it penetrates the blockage, the catheter (20) being equipped at its proximal end with means (23) for rotating the catheter about its axis as it is advanced into the artery or similar vessel.

4. A catheter system according to claim 3, characterised in that the tool member (30, 60, 96, 101) is provided with an external thread which draws the end piece further into the blockage as the end piece is rotated by the rotation of the catheter.

5. A catheter system according to claim 4, characterised in that the tool member is in the form of a pointed conical auger with the screw thread formed externally on the conical surface of the auger.

6. A catheter system according to any one of claims 1 to 4, characterised in that the catheter (20) is tubular.

7. A catheter system according to claim 6, characterised in that the tool member (96, 101) has an axial passageway therein communicating with the lumen of the catheter for the passage of a guide wire therethrough.

8. A catheter system according to claim 7, comprising a guide wire located in the lumen of the catheter and extending through the axial passageway in the tool member (96, 101) so as to

- project forwardly a short distance, the distal end of the guide wire having a pointed end or end piece (99) which forms the pointed nose of the tool member (101).
9. A catheter system according to claim 8, characterised in that the end piece (99) on the guide wire is a sharply pointed conical member having a rearwardly directed shoulder (100) which abuts an end face of the tool member (101).
10. A catheter system according to any one of claims 1 to 9, which includes a centering catheter (40, 42, 50, 70, 80, 88, 91) insertable into the artery or similar vessel through the said incision and to be advanced along the artery or similar vessel until the distal end of the centering catheter is adjacent the blockage, said centering catheter having a central lumen extending the length of the centering catheter and through which the catheter (20) carrying the tool member (30, 60, 96, 101) can be advanced to bring the tool member to the site of the blockage.
11. A catheter system according to claim 10, wherein the centering catheter (40) is of a uniform outer diameter throughout its length that lies within the patient's body.
12. A catheter system according to claim 10, wherein the centering catheter (70) has a bulge (72) near its distal end to facilitate centering of the centering catheter's distal end (74) in the artery.
13. A catheter system according to claim 12, wherein the bulge (72) is resiliently compressible to permit the insertion thereof into the patient's body through a guiding catheter or sheath pre-inserted into the patient's body.
14. A catheter system according to claim 10 wherein the distal end portion (86) of the centering catheter (82) is formed with a plurality of radially arranged flexible spokes connected to a distal end ring, the said spokes bulging outwardly when the distal end ring of the centering catheter is pushed against the blockage.
15. A catheter system according to claim 10 wherein the centering catheter (40) carries an inflatable balloon (46) adjacent its distal end, the balloon being inflatable by means of an inflating gas introduceable therein through a gas flow lumen (44) extending the length of the catheter (20).
16. A catheter system according to any one of claims 10 to 15, wherein the centering catheter (87) has a flat wire helical coil (89) positioned therein in the central lumen and extending along at least a portion of the length of the lumen.
17. A catheter system according to any one of claims 10 to 16 wherein the centering catheter (42) has a fluid tight seal (47) at its proximal end which makes a fluid seal against the outer surface of the tool carrying catheter (22).
18. A catheter system according to any one of claims 10 to 17 wherein the proximal end of the tool carrying catheter (20) carries a series of axially spaced markings indicating the distance by which the tool (30, 96) projects beyond the distal end of the centering catheter.
19. A catheter system according to any one of claims 10 to 18 wherein the centering catheter has a radiopaque marker (93) at or near its distal end.
20. A catheter system according to any one of claims 1 to 19, wherein the tool has a lubricious coating on its surface to facilitate the advancement of the tool into the blockage.
21. A catheter system according to any one of claims 1 to 20, wherein at least part of the tool member at the distal end of the tool carrying catheter is formed from radiopaque metal.

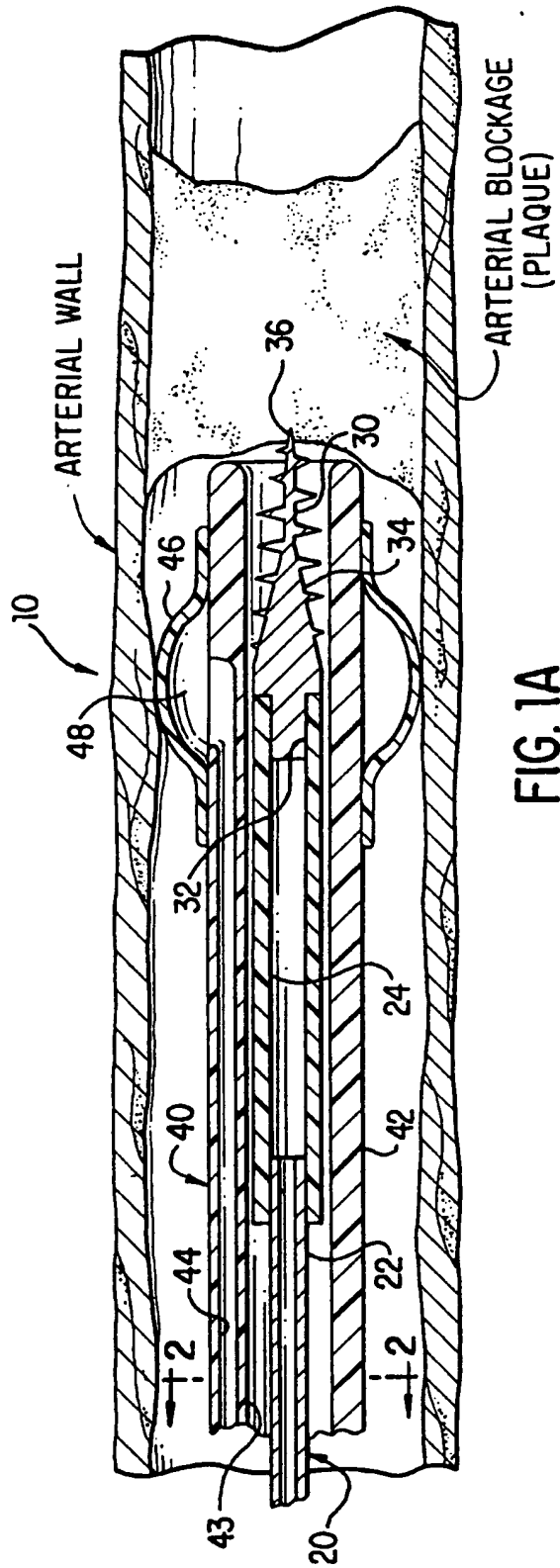


FIG. 1A

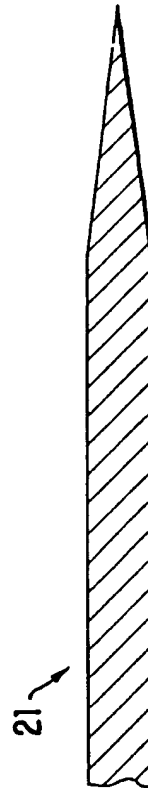
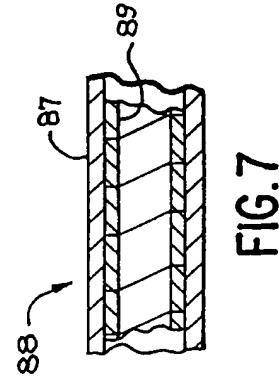
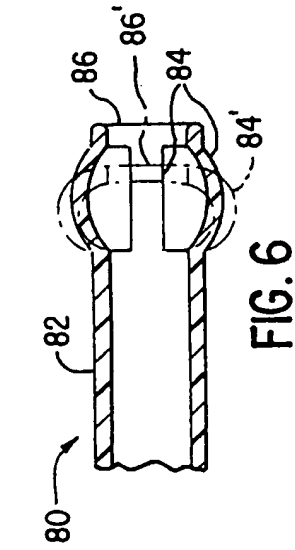
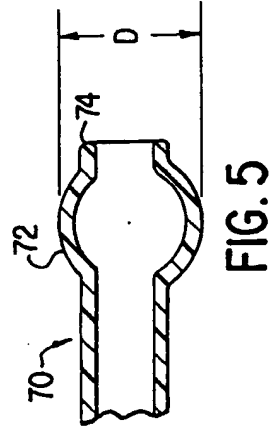
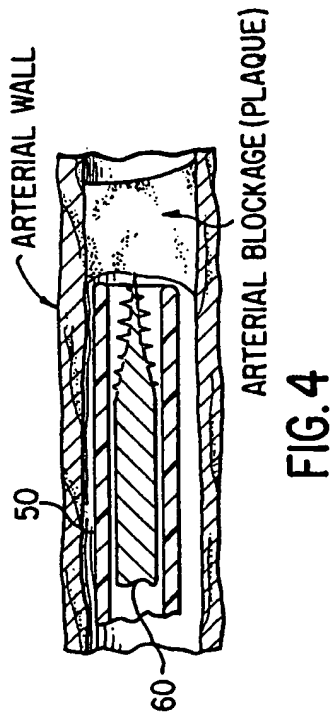
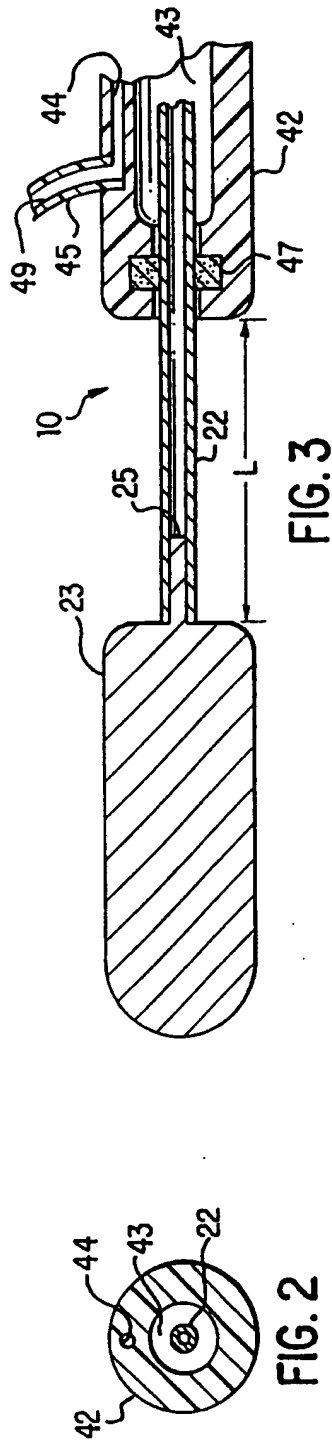


FIG. 1B



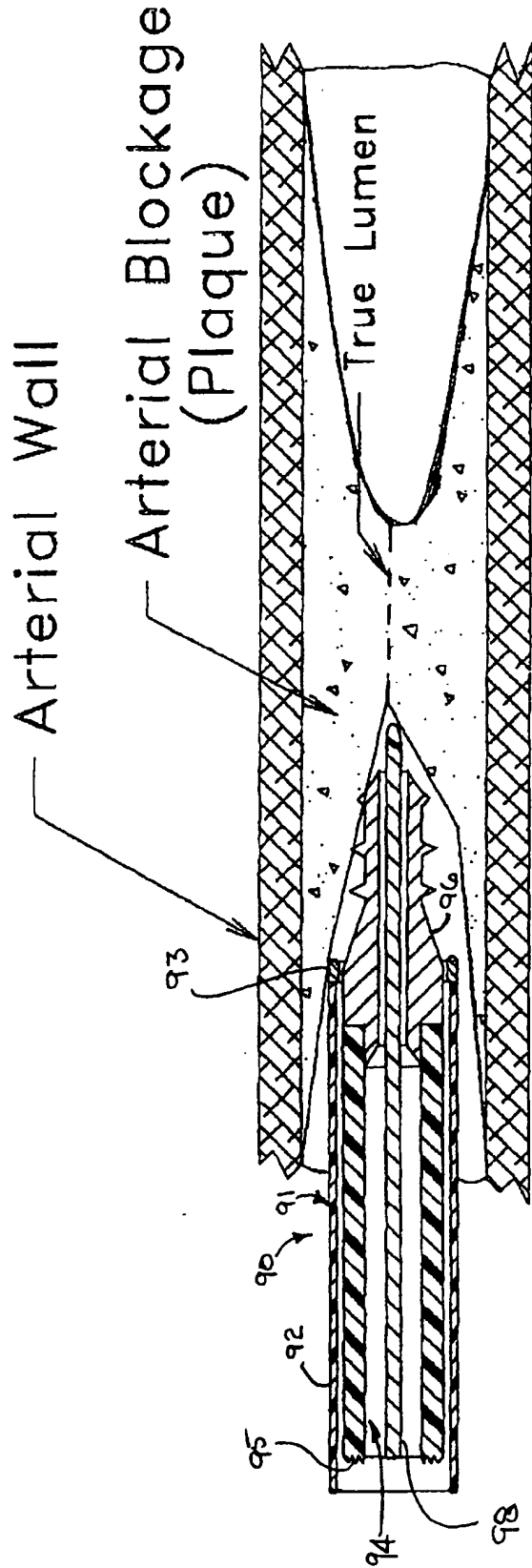


FIG. 8

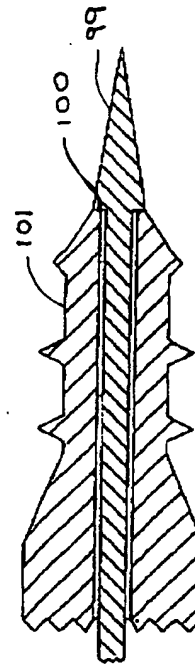


FIG. 9



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 93 30 9280

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
Y	EP-A-0 373 927 (MEDTRONIC) * column 5, line 8 - line 21 * * column 6, line 20 - line 38; figure 3 * ---	1-21	A61B17/22
Y	EP-A-0 360 791 (WICHART) * claim 1 * ---	1-21	
A	EP-A-0 448 859 (SHIBER) * column 3, line 36 - line 38 * * line 46 - line 49 * * column 8, line 1 - line 5 * * column 10, line 4 - line 42 * ---	1-4,6,7 10-15	
A	US-A-4 994 067 (SUMMERS) * column 3, line 45 - line 48 * ---	7-9	
A	EP-A-0 420 395 (INTERVENTIONAL TECHNOLOGIES INC) * column 8, line 17 - line 19 * ---	17	
A	DE-U-84 03 321 (OLYMPUS WINTER & IBE GMBH) * page 9, paragraph 4 * ---	18	TECHNICAL FIELDS SEARCHED (Int.Cl.6)
A	EP-A-0 380 102 (ADVANCED CARDIOVASCULAR SYSTEMS, INC.) * page 4, line 10 - line 14 * -----	19-21	A61B A61M
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 28 February 1995	Examiner Glas, J
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document I : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons ----- & : member of the same patent family, corresponding document			